K122616

PROWESS

510(k) Summary

DEC 2 1 2012

As required by 21 CFR Part 807.92

August 23, 2012

1. **Submitter:**

Prowess, Inc.
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Concord, CA. 94520

Contact Person:

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Device Manufacturer:

Prowess, Inc.
1844 Clayton Road
Concord, CA. 94520

2. **Device Trade Name:** Panther OIS|R&V

Classification Name: Medical charged-particle radiation therapy system (21 CFR § 892.5050), Product Code MUJ, Class II

Establishment Reg. No.: 2939248

Common Name: Oncology Information System
Radiation Therapy Record and Verify System

3. **Predicate Devices:**

a) IMPAC Medical Systems, Inc's (Elekta) MOSAIQ – K120067

b) Varian Medical System Inc.'s ARIA Radiation Oncology – K093527

c) Varian Medical System's 4D Integrated Treatment Console (4DITC) – K091132

d) Prowess Inc's Puma (version 1.0) – K100801 (**as previously cleared)*

4. **Device Description**

Panther OIS|R&V is medical device software which allows the user to deliver radiation treatment on linear accelerator to a patient. The software has been developed to be a record and verify system that also manages oncology medical information in order to simplify the

oncologist administrative tasks and to optimize the quality of patient treatment. It is a Windows® based system, which uses a single database that can be accessed by any Panther OIS|R&V client station in the treatment facility. Additionally, Panther OIS|R&V is capable of performing such functions as:

- Importing treatment plans in DICOM or RTP format
- Downloading of beams contained in the treatment plans to the linear accelerator
- Verifying that the beams from the treatment plan are correctly set up on the linear accelerator
- Recording treatments delivered by the linear accelerator
- Managing patient schedules
- Managing schedules for resources such as treatment machines and personnel
- Maintaining a central repository of treatment plans and records
- Documenting, monitoring and updating treatments and treatment plan information
- Performing administrative tasks such as patient management.
- Data locking or warning to prevent simultaneous access to patient (Tx) data
- Reports of patients and treatment history
- Manual Recording of treatment beams
- Late Resumption of incomplete treatments

5. Intended Use

Panther OIS|R&V is an information management system used to manage medical data and clinical workflow in a hospital or clinic. To support radiation oncology users, it allows the user to:

- Enter or import, modify, store and archive treatment plans and images from treatment planning systems.
- Import, view, manipulate, enhance, annotate, store, and archive radiological images.
- Select and provide radiation treatment plans to a radiation treatment delivery system for patient treatment.
- Store and view treatment records provided by the radiation treatment delivery system.
- Monitor and track treatment progress.
- When Panther OIS|R&V is acting as an R&V system, verify the delivery device's settings against the planned parameters, record the treatment parameters settings and prevent treatment if the parameters are out of tolerance.

6. Summary of Comparisons to Predicate Devices

Panther OIS|R&V is substantially equivalent to the predicate devices, IMPAC Medical Systems, Inc's (Elekta) MOSAIQ (K120067), Varian Medical System Inc.'s ARIA Radiation Oncology (K093527) and 4D Integrated Treatment Console (K091132), and Prowess Inc.'s Puma (K100801), for purposes of FDA clearance for commercial distribution, as demonstrated and documented in this premarket notification submission. It has the same intended use and indications for use. In addition, the rationalization for substantial equivalence is further evidenced through discussion

of similar technological characteristics between Panther OIS|R&V and the predicates, as well as test results, which prove that Panther OIS|R&V is as safe and effective as the predicate devices.

7. Summary of Technological Considerations

Panther OIS|R&V has many of the same technological characteristics as the predicate devices. There is a limited amount of distinguishing factors when comparing Panther OIS|R&V to the predicates, and those features that are different do not affect safety or effectiveness. Panther OIS|R&V provides a set of similar functionalities in such a manner that it is substantially equivalent to the MOSAIQ system and the combined ARIA+4DITC.

8. Summary of Non-clinical Tests

A hazard analysis was completed for Panther OIS|R&V. Methods for preventing such hazards follow Prowess Inc. and ISO 14971 Risk Management process. Verification and validation of the software was conducted in house according to the Verification and Validation (V&V) Protocol, *Panther OIS|R&V Testing Protocol*. Test results have been included in this submission, showing documented evidence of successful fulfillment of pass/fail criteria. These tests have demonstrated that Panther OIS|R&V has met its predetermined specifications, is substantially equivalent in performance as compared to the predicate devices, functions as intended, and is safe and effective for its specified use.

9. Summary of Clinical Tests

Although clinical testing is not required to demonstrate substantial equivalence in safety and effectiveness, we elected to conduct testing at Community Memorial Hospital. We feel that no matter how carefully a product is tested at the manufacturer's facility, such testing cannot replace actual use of the device in a clinical setting. As such, we consider both in-house testing and beta/external testing at a user site during device development.

10. Labeling

The CD media labeling, Instructions for Use and User Manual are provided this submission. The entire User Manual, in digital format, is also included in the software media and can be viewed as part of the on-line help.

Commercial and marketing materials have been included in this submission.

Product labels comply with 21 CFR 1040.10 and 1040.11 as applicable. In addition, labeling complies with applicable requirements of 21 CFR 801, including the requirement that the device be provided with adequate directions for use.

11. Summary of Safety and Effectiveness Information

a. Prowess, Inc. is a registered medical device establishment, whose quality system meets the requirements of ISO 13485, the Medical Device Directive 93/42/EEC Annex II and FDA's Quality System Regulation, 21 CFR 820.

b. Panther OIS|R&V was designed and implemented according to the established design and development as well as quality management procedures of Prowess Inc. In addition, design and development of the medical device software complies with internationally recognized standards including ISO 14971:2007Medical devices –

Application of risk management to medical devices, IEC 62304 Medical device software – Software life cycle processes, and IEC 62274 Medical electrical equipment – Safety of radiotherapy record and verify systems.

c. The management of the company is committed to the highest standards of quality management. The Quality Management System is subject to regular, planned and documented audits by external consultants and by the FDA.

d. A comprehensive risk analysis has been conducted. Detailed methods of mitigating these potential risks have been identified by the development team, and verified by clinical physicists contracted by Prowess and determined to be adequate.

e. The software has been verified and validated based on established testing plans. The functionalities have been tested by in-house test engineers. In addition to in-house testing, the system was also tested by our beta-site using clinical cases.

f. Key safety features of Panther OIS|R&V include:

- Defined privileges to access specified areas of the functionality for different roles and users
- Patient identification by an ID photo associated to the patient during registration
- Data locking and messaging to prevent simultaneous access to patient treatment data
- Verifying that the beams contained in the treatment plan are correctly set up on the linear accelerator

g. Panther OIS|R&V includes features specifically designed to protect confidential patient health information in accordance with the HIPAA regulations, including such security measures as password protection and access privilege set up and modification. By restricting access and other rights, patient health information can be safeguarded against deletion and/or alteration.

h. Steps and precautions for the safe and effective use are included in the Instructions for Use and User Manual. Training by a Prowess specialist may also be provided as at the time of product distribution, when requested by the customer.

12. Level of Concern

As medical device software, the submission for a follow Panther OIS|R&V FDA's *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.* Since prior to mitigation of hazards, a failure of the software device could result in death or serious injury to a patient, it has been determined that the software correlates to a Major Level of Concern, and as such, the associated documentation is included in this submission.

13. Conclusions

Panther OIS|R&V is substantially equivalent to the predicate devices for the purposes of FDA clearance for commercial distribution. It has the same intended use and similar technical characteristics. The software has been found to perform as intended and the benefits to patient and user outweigh any inherent risks, which has been demonstrated via in-house testing as well

as in our field tests. Its use does not raise any new or different safety and effectiveness concerns when compared to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 21, 2012

Ms. Rachel Scarano
Regulatory Affairs Manager
Prowess Inc.
1844 Clayton Road
CONCORD, CA 94520

Re: K122616
Trade/Device Name: Panther OIS|R&V
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 16, 2012
Received: November 21, 2012

Dear Ms. Scarano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris -S

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122616

Device Name: Panther OIS|R&V

Indications for Use:

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Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
2012.12.21 16:13:44 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) k122616